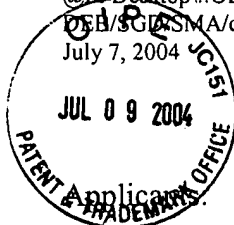


July 7, 2004



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Stavros C. Manolagas, Robert L. Jilka, Robert S. Weinstein and Teresita Bellido

Application No.: 10/743,360 Group Art Unit: 1614
Filed: December 22, 2003 Examiner: Not Assigned
Confirmation No.: 9347

Title: METHODS OF SCREENING FOR APOPTOSIS-CONTROLLING AGENTS
FOR BONE ANABOLIC THERAPIES AND USES THEREOF

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
7/7/04	<i>Christina McSweeney</i>
Date	Signature
<i>Christina McSweeney</i>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/413,785, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 10/829,028, by Stavros C. Manolagas, Robert L. Jilka, Robert S. Weinstein, Teresita Bellido, Donald Bodenner, and Stavroula Kousteni, filed April 21, 2004, Docket No.: 3650.1006-010

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

[X] A copy of each above-cited application, including the current claims, is enclosed.

[] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Susan M. Abelleira

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Dated: July 7, 2004

PTO-1449 REPRODUCED

OUR DOCKET NO.
3650.1004-008APPLICATION NO.
10/743,360FIRST NAMED INVENTOR
Stavros C. ManolagasFILING DATE
December 22, 2003EXAMINER
Not AssignedCONFIRMATION NO.
9347GROUP
1614INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

July 7, 2004

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,588,716	DeLuca, H.F., <i>et al.</i>	05-13-1986
	AB	4,833,125	Neer, R.M., <i>et al.</i>	05-23-1989
	AC	5,118,667	Adams, S.W., <i>et al.</i>	06-02-1992
	AD	5,164,368	Recker, R.R., <i>et al.</i>	11-17-1992
	AE	5,510,370	Hock, J.M., <i>et al.</i>	04-23-1996
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	AG	5,747,456	Chorev, M., <i>et al.</i>	05-05-1998
	AH	5,821,225	Vickery, B.H., <i>et al.</i>	10-13-1998
	AI	5,955,425	Morley, P., <i>et al.</i>	09-21-1999
	AJ	5,977,070	Piazza, C.T., <i>et al.</i>	11-02-1999
	AK	6,660,468 B1	Manolagas, <i>et al.</i>	12-09-2003
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	AB2			
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	FIRST NAMED INVENTOR Stavros C. Manolagas		FILING DATE December 22, 2003
	EXAMINER Not Assigned	CONFIRMATION NO. 9347	GROUP 1614

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	WO 94/03201	02-17-1994	Hilliker, S.		
	AM					
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AR	Aarden, E.M., <i>et al.</i> , "Function of Osteocytes in Bone," <i>J. Cell. Biochem.</i> 55: 287-299 (1994).
	AS	Amling, M., <i>et al.</i> , "Bcl-2 Lies Downstream of Parathyroid Hormone-related Peptide in a Signaling Pathway that Regulates Chondrocyte Maturation During Skeletal Development," <i>Journal of Cell Biology</i> 136: 205-213 (1997).
	AT	Bellido, T., <i>et al.</i> , "Overexpression of Bcl-2 Renders Osteoblastic Cells Refractory to Glucocorticoid-Induced Apoptosis," <i>Bone</i> 23: S324 (1998).
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	AY	Franceschi, R.T., <i>et al.</i> , "Regulation of Type I Collagen Synthesis by 1,25-Dihydroxyvitamin D3 in Human Osteosarcoma Cells," <i>Journal of Biological Chemistry</i> 263: 18938-18945 (1988).
	AZ	Hsu, S., <i>et al.</i> , "Color Modification of Diaminobenzine (DAB) Precipitation by Metallic Ions and its Application for Double Immunohistochemistry," <i>J. of Histochemistry and Cytochemistry</i> 30: 1079-1082 (1982).
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	AS2	Jilka, R.L., <i>et al.</i> , "Increased Osteoclast Development After Estrogen Loss: Mediation by Interleukin-6," <i>Science</i> 257: 88-91 (1992).
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AU2	Jilka, R.L., <i>et al.</i> , "Loss of Estrogen Upregulates Osteoblastogenesis in the Murine Bone Marrow, Evidence of Autonomy from Factors Released During Bone Resorption," <i>The American Society for Clinical Investigation, Inc. 101</i> : 1942-1950 (1998).
	AV2	Jilka, R.L., <i>et al.</i> , "PTH Increases Bone Formation by Postponing Osteoblast Apoptosis, Not By Increasing Precursor Proliferation," <i>Bone 23</i> : S519 (1998).
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	AX2	Kato, Y., <i>et al.</i> , "Establishment of an Osteocyte-Like Cell Line, MLO-Y4," <i>Journal of Bone and Mineral Research 12</i> : 2014-2023 (1997).
	AY2	Lane, N.E., <i>et al.</i> , "Parathyroid Hormone Treatment Can Reverse Corticosteroid-induced Osteoporosis," <i>Journal of Clinical Investigation 102</i> : 1627-1633 (1998).
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	AT3	Parfitt, A.M., <i>et al.</i> , "Bone Histomorphometry: Standardization of Nomenclature, Symbols, and Units," <i>Journal of Bone and Mineral Research 2</i> : 595-610 (1987).
	AU3	Reeve, J., <i>et al.</i> , "Anabolic Effect of Human Parathyroid Hormone fragment on Trabecular Bone in Involutional osteoporosis: a Multicentre Trial," <i>British Medical Journal 280</i> : 1333-1390 (1980).
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AX3	Sudo, H., <i>et al.</i> , "In Vitro Differentiation and Calcification in a New Clonal Osteogenic Cell Line Derived from Newborn Mouse Calvaria," <i>Journal of Cell Biology</i> 96: 191-198 (1983).	
AY3	Tam, C.S., <i>et al.</i> , "Parathyroid Hormone Stimulates the Bone Apposition rate Independently of Its Resorptive Action: Differential Effects of Intermittent and Continuous Administration," <i>Endocrinology</i> 110: 506-512 (1982).	
AZ3	Thornberry, N.A., <i>et al.</i> , "Caspases: Enemies Within," <i>Science</i> 281: 1312-1316 (1998).	
AR4	Vickery B.H., <i>et al.</i> , "RS-66271, a C-Terminally Substituted analog of Human Parathyroid Hormone-Related Protein (1-34), Increases Trabecular and Cortical Bone in Ovariectomized, Osteopenic Rats," <i>Journal of Bone and Mineral Research</i> 11: 1943-1951 (1996).	
AS4	Weinstein, R.S., <i>et al.</i> , "Inhibition of Osteoblastogenesis and Promotion of Apoptosis of Osteoblasts and Osteocytes by Glucocorticoids," <i>The Journal of Clinical Investigation</i> 102: 274-282 (1998).	
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AW4	Ferretti, J.L., <i>et al.</i> , "Perspectives on Osteoporosis Research: Its Focus and Some Insights from a New Paradigm," <i>Calcif. Tissue Int.</i> 57: 399 (1995).	
AX4	Forrest, S.M., <i>et al.</i> , "Characterization of an Osteoblast-like Clonal Cell Line Which Responds to both Parathyroid Hormone and Calcitonin," <i>Calcif. Tissue Int.</i> 37: 51-56 (1985).	
AY4	Gohel, A., <i>et al.</i> , "Glucocorticoids Induce Apoptosis in Osteoblasts by the Regulation of Bcl-2, BAX and Other Cell Cycle Factor," <i>Journal of Bone and Mineral Research</i> . Abstract F234: S284 (1997).	
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AR5	Hughes, D.E., <i>et al.</i> , "Bisphosphonates Promote Apoptosis in Murine Osteoclasts In Vitro and In Vivo," <i>Journal of Bone and Mineral Research</i> 10 (10): 1478-1487 (1995).	
AS5	Iida-Klein, A., <i>et al.</i> , "Effects of Calcitonin on 3', 5'-Cyclic Adenosine Monophosphate and Calcium Second Messenger Generation and Osteoblast Function in UMR 106-06 Osteoblast-Like Cells," <i>Endocrinology</i> 130(1): 381-388 (1992).	
AT5	Jilka, R.L., <i>et al.</i> , "Dexamethasone Promotes Apoptosis of Osteoblast Progenitors in Murine Bone Marrow Cultures: Antagonism by IL-6 Type Cytokines," <i>Journal of Bone and Mineral Research</i> 12(Supp): S455, Abstract No. S411 (1997).	
AU5	Jilka, R.L., <i>et al.</i> , "Increased Bone Formation by Prevention of Osteoblast Apoptosis with Parathyroid Hormone," <i>Journal of Clinical Investigation</i> 104(4): 439-466 (1999).	
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AY5	Manolagas, S.c., <i>et al.</i> , "Opposite Effects of Estrogen on the Life Span of Osteoblasts/Osteocytes Versus Osteoclasts In Vivo and In Vitro: An Explanation of the Imbalance Between Formulation and Resorption in Estrogen Deficiency," <i>Journal of Bone and Mineral Research</i> 14: Abstract No. S169 (1999).	
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AT6	Plotkin, L.I., <i>et al.</i> , "Bisphosphonates Prevent Glucocorticoid-Induced Apoptosis of Osteocytes in Vitro: a Putative Mechanism Influencing Mechanosensing," <i>Bone</i> 23: S157 (1998).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AU6	Plotkin, L.I., <i>et al.</i> , "Prevention of Osteocyte and Osteoblast Apoptosis by Bisphosphonates and Calcitonin," <i>Journal of Clinical Investigation</i> 104(10): 1363-1374 (1999).	
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AX6	Short, B.G., <i>et al.</i> , "Automated Double Labeling of Proliferation and Apoptosis in Glutathione S-Transferase-Positive Hepatocytes in Rats," <i>Journal of Histochemistry & Cytochemistry</i> 45(9): 1299-1305 (1997).	
AY6	Verbeijen, M.H., <i>et al.</i> , "Parathyroid Hormone Activates Mitogen-activated Protein Kinase via cAMP-mediated Pathway Independent of Ras," <i>Journal of Biological Chemistry</i> 272(6): 3423-3429 (1997).	
AZ6	Weinstein, R.S., <i>et al.</i> , "The Effects of Androgen Deficiency on Murine Bone Remodeling and Bone Mineral Density are Mediated via Cells of the Osteoblastic Lineage," <i>Endocrinology</i> 138(9): 4013-4021 (1997).	
AR7	Schwartz, Z., <i>et al.</i> , "Differential Regulation of Prostaglandin E2 Synthesis and Phospholipase Activity by 1,25-(OH)2D3 in Three Osteoblast-like Cell Lines (MC-3T3-E1, ROS 17/2.8, and MG-63)," <i>Bone</i> 13(1): 51-8 (1992).	
AS7	Lane, J.M., <i>et al.</i> , "Intermittent Treatment with Human Parathyroid Hormone (hPTH[1-34]) Increased Trabecular Bone Volume but Not Connectivity in Osteopenic Rats," <i>Journal of Bone and Mineral Research</i> 10(10): 1470-1477 (1995)	
AT7	Gunness, M., <i>et al.</i> , "Anabolic Effect of Parathyroid Hormone on Cancellous and Cortical Bone Histology," <i>Bone</i> : 14, 277-281 (1993).	
AU7	Hill, P.A., <i>et al.</i> , "Multiple Extracellular Signals Promote Osteoblast Survival and Apoptosis," <i>Endocrinology</i> : 138(9), 3849-3858 (1997).	
AV7	Lecka-Czernik, B., <i>et al.</i> , "Cellular and Molecular Biomarkers Indicate Precocious In Vitro Senescence in Fibroblasts from SAMP6 Mice," <i>Journal of Gerontology</i> : 52A(6), B331-B336 (1997).	
AW7	Meng, X.W., <i>et al.</i> , "Temporal Expression of the Anabolic Action of PTH in Cancellous Bone of Ovariectomized Rats," <i>Journal of Bone and Mineral Research</i> : 11(4), 421-429 (1996).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AX7	Okamoto, Y., "Femoral Peak Bone Mass and Osteoclast Number in an Animal Model of Age-Related Spontaneous Osteopenia," <i>The Anatomical Record</i> : 242, 21-28 (1995).
	AY7	Cornish, J., "An In Vivo Model for the Rapid Assessment of the Local Effects of Parathyroid Hormone on Bone Histomorphometry," <i>Bone</i> : 17(4) Supp., 249S-254S (1995).
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EXAMINER	DATE CONSIDERED
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